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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,602	09/17/2001	Bernadette Yon-Hin	1348.017USQ	5721
7590	09/27/2004			EXAMINER
George W Rauchfuss Jr Ohlandt Greeley Ruggiero & Perle Tenth Floor One Landmark Square Stamford, CT 06901-2682			OLSEN, KAJ K	
			ART UNIT	PAPER NUMBER
			1753	
DATE MAILED: 09/27/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/831,602	YON-HIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kaj K Olsen	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Priority***

1. With respect to the applicant's claimed priority, applicant is entitled to 371 priority to PCT/GB99/03764. Applicant is also entitled to priority under 120 to US application 09/445,154. However, applicant is not entitled to priority to GB 9711395.5 of 6/4/1997 because this priority claim had not been made in the PCT application. See MPEP, 37 CFR 1.55.
2. Applicant also provided a new disclosure and claims for the application on 5-10-2001. In particular, the new submitted disclosure has 18 pages of specification with 19 claims and 2 figures in comparison with the PCT application that has 6 pages of specification and 12 claims and no figures. Applicant is only permitted to make amendments to 371 applications under Article 19 during the international stage. Because this new disclosure was not introduced during the international stage, that new disclosure cannot be entered (see MPEP 35 U.S.C. 371). Because this disclosure cannot be entered, this examination will be based on the disclosure and claims of the PCT application (i.e. based on the 6 pages of specification and 12 claims). The other disclosure will remain in the file, but will not be considered.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1753

4. Claims 1-5 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/02487.

5. WO '487 discloses a test strip comprising a support 2 carrying an active electrode 4, a counter electrode 5, and a layer of material 3 or 13 within which a small volume of liquid can be tested. WO '487 further discloses an analyte specific reagent 11 that coats a well 9 formed by the layer of material. See fig. 1 and 4 and p. 8, lines 1-11. With respect to the active specific reagent, see table 1. With respect to the measuring claims, see p. 10, line 31 and table 1.

6. Claims 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 593,096 A2.

7. EP '096 discloses a flexible tape of material within which liquid can be distributed and on which are coated discrete areas of at least one component of a redox reaction. See p. 6, line 57 through p. 7, line 3. With respect to the mesh, see p. 6, lines 20-31.

#### *Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '096 in view of Harttig et al (USP 5,679,311).

11. EP '096 set forth all the limitations of the claims, but did not explicitly recite a container for the flexible tape. Hartttig teaches in an alternate bioassay the use of a container for holding a roll of test mechanisms, which minimizes contamination. See fig. 2a, the abstract and col. 5, lines 7-28. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Harttig for the flexible tape of EP '096 in order to provide a convenient means for providing a plurality of test devices that minimizes the contamination of those test devices.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753  
September 23, 2004



KAJ K. OLSEN  
PRIMARY EXAMINER